H 1 Cont'd.

35. (New) The purified immunological complex of claim 19, wherein the peptide has the sequence of HIV-1 ORF-4. --

REMARKS

Reconsideration of this application is respectfully requested. Applicants have added new claims 20-35, which are derived from, and dependent on, claims 11, 15, 17, and 19. No new matter enters by amendment.

As requested by the Examiner, applicants have enclosed a copy of the Judgment in Interference No. 102,822 (Paper No. 300), which indicates that applicants were judged not to be entitled to a patent containing claims 30, 31, 56-61, 109-115, and 132, corresponding to Counts 2-6 in that interference. Applicants have also enclosed copies of Paper Nos. 271, 282, and 289 in Interference No. 102,822, which provide the language of Counts 2-6, and a copy of claims 30, 31, 56-61, 109-115, and 132.

Claims 11 and 17 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to the skilled artisan that the inventors had possession of the claimed invention at the time the application was filed. The Examiner contends that applicants' description is insufficient because applicants did not actually express and purify the antigens of interest and actually prepare specific immunological reagents. Applicants traverse the rejection.

Applicants disagree with the Examiner's position that a working example is required to show possession of the claimed antibodies. This requirement is inconsistent with current legal precedent. For example, the Court of Appeals for the Federal Circuit has held that the mere fact that something has not previously been done is not a

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sufficient basis for rejecting all applications purporting to disclose how to do it. *Gould v. Quigg*, 3 U.S.P.Q.2d 1302, 1304 (1987). If a working example is required to show possession of an invention, the holding in *Gould* would be moot. Accordingly, the Office's basis for this rejection is in error, and the rejection should be withdrawn.

Furthermore, the Supreme Court has explicitly stated that "it is well settled that an invention may be patented before it is reduced to practice." *Pfaff v. Wells Electronics Inc.*, 48 U.S.P.Q.2d 1641, 1644 (1998). Clearly, a working example (*i.e.*, reduction to practice) cannot be required to show possession of an invention. The M.P.E.P. acknowledges this fact. M.P.E.P. § 2163 ("Possession may be shown in a variety of ways including description of an actual reduction to practice or by showing that the invention was 'ready for patenting' . . . .").

In *Pfaff*, the Court indicated that an invention was "ready for patenting" when the inventor prepared a description of the invention that was sufficiently specific to enable a person skilled in the art to practice the invention. 48 U.S.P.Q.2d at 1647. The Court found that Pfaff's invention was ready for patenting when Pfaff made drawings that fully disclosed the invention, not when a working example was made. *Id.* The Court's reasoning in *Pfaff* is directly applicable to applicants' invention.

Pfaff's invention was "ready for patenting" without a working example. *Id.* at 1647. Consequently, Pfaff must have had possession of the invention without a working example. Likewise, applicants can have possession of their invention without a working example. What applicants need is a description of the invention that is sufficiently specific to enable a person skilled in the art to practice the invention. *See Id.* at 1647.

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Applicants' specification provides such a description. As acknowledged by the Examiner (Paper No. 31 at 4), the specification provides the complete sequence of HIV-1 and identifies the open reading frames recited in applicants' claims. (Specification at 12-13 and Figs. 2-12.) The specification describes that "DNA fragments corresponding to genes can be cloned into expression vectors for *E. coli*, yeast- or mammalian cells and the resultant proteins purified." (*Id.* at 14, lines 2-4.) The expression of proteins from cloned DNAs in *E. coli*, yeast, and mammalian cells was well-known at the time the application was filed. (*See* Exhibits 1-3.)

In addition, the specification describes that:

> The invention also relates to the polypeptides themselves which can be expressed by the different DNAs of the inventions, particularly by the ORFs or fragments thereof, in appropriate hosts, particularly prokaryotic or eukaryotic hosts, after transformation thereof with a suitable vector previously modified by the corresponding DNAs.
>
> These polypeptides can be used as diagnostic tools, particularly for the detection of antibodies in biological media, particularly in sera or tissues of persons afflicted with pre-AIDS or AIDS, or simply carrying antibodies in the absence of any apparent disorders. Conversely, the different peptides according to this invention can be used themselves for the production of antibodies, preferably monoclonal antibodies specific of the different peptides respectively. For the production of hybridomas secreting said monoclonal antibodies conventional production and screening methods are used.

(*Id.* at 15, lines 18-35.) The production of antibodies against purified viral antigens was well-known at the time the application was filed. (*See* Exhibit 4.) PUTATIVE

Applicants' specification teaches the nucleotide sequence of the ORFs recited in applicants' claims, to express the polypeptides encoded by these ORFs, and to make antibodies against these polypeptides. Applicants' description is sufficiently specific to enable a person skilled in the art to practice the invention. Consequently, applicants'

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claimed antibodies are ready for patenting. *See Pfaff,* 48 U.S.P.Q.2d at 1647. Accordingly, no working example is required for applicants to patent the claimed antibodies. *See id.* at 1644.

In addition, the Examiner's position is inconsistent with the Office's Synopsis of Application of Written Description Guidelines, which on pages 59-60 (copy attached as Exhibit 5) indicates that a claim to an isolated antibody capable of binding to an antigen fulfills the written description requirement in the absence of a working example of the production of antibodies that specifically bind to the antigen. In *Enzo Biochen, Inc., v. Gen-Probe, Inc.*, 63 U.S.P.Q.2d 1609, 1613 (2002), the Court of Appeals for the Federal Circuit adopted the Office's standard for determining compliance with the written description requirement, specifically citing the Office's finding of compliance with § 112, first paragraph, in this particular example of a claim to an isolated antibody. Accordingly, no working example is required for applicants' claims to isolated antibodies to fulfill the written description requirement.

Moreover, the Examiner has not met his burden with respect to this rejection. M.P.E.P. § 2163.04 states:

> A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Wertheim*, 541 F.2d at 263, 191 USPQ at 97.

The Examiner has not provided a reasonable basis to challenge the adequacy of applicants' written description. As detailed above, the mere absence of a working

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example is not a sufficient basis. In addition, the Examiner's questioning of whether applicants' claimed ORFs are *bona fide* ORFs (Paper No. 31 at 5) is not supported by any evidence of record. Rather, as indicated in *Fundamental Virology* (Exhibit 6), HIV-1 ORF-Q (*vif*), ORF-R (*nef*), ORF-1 (*vpr*), and ORF-4 (*vpu*) are *bona fide* ORFs. Thus, there is no evidence of record that a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. Accordingly, applicants respectfully request withdrawal of the rejection.

Claims 15 and 19 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to the skilled artisan that the inventors had possession of the claimed invention at the time the application was filed. The Examiner contends that applicants' description is insufficient because "there is no indication anywhere that isolated and purified immunological complexes were even contemplated or prepared." (Paper No. 31 at 8.) Applicants traverse the rejection.

As discussed above, no working example is required for applicants to have possession of the claimed immunological complexes. Moreover, the specification describes that polypeptides expressed from HIV-1 ORFs "can be used as diagnostic tools, particularly for the detection of antibodies in biological media, particularly in sera or tissues of persons afflicted with pre-AIDS or AIDS, or simply carrying antibodies in the absence of any apparent disorders." (Specification at 15, lines 25-30.) Having read this passage from the specification, the skilled artisan would immediately recognize that applicants contemplated making and using the claimed immunological complexes in order to achieve diagnosis of persons afflicted with pre-AIDS or AIDS, or simply carrying

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antibodies in the absence of any apparent disorders. Accordingly, applicants respectfully request withdrawal of the rejection.

Applicants respectfully submit that this application is in condition for allowance. In the event that the Examiner disagrees, he is invited to call the undersigned to discuss any outstanding issues remaining in this application in order to expedite prosecution.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: April 23, 2003

By: _____

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